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Alliance for Pharmacy Compounding

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Nebraska Board of Pharmacy
Nebraska Department of Health and Human Services
Licensure Unit
301 Centennial Mall South
Lincoln, NE 68509

Re: Interpretation of Neb. Rev. Stat. §38-2867.01 Regarding Compounded Medications from 503B Facilities

Members of the Nebraska Board of Pharmacy:

On behalf of the Alliance for Pharmacy Compounding, we respectfully write to express our concerns regarding the Board's current interpretation of Neb. Rev. Stat. §38-2867.01, which appears to prohibit 503A compounding pharmacies from purchasing compounded medications from 503B outsourcing facilities for the purpose of subsequent patient-specific dispensing.

We understand the Board's position is based on the language in §38-2867.01(1)(c), which limits office-use compounding to activities "not for resale." However, we wish to highlight that the transaction between a 503B outsourcing facility and a 503A pharmacy is not a resale in the conventional sense, nor is it an office-use scenario. Rather, it is a supply chain transaction in which a 503A pharmacy sources compounded preparations from a registered 503B facility—a facility regulated under section 503B of the Federal Food, Drug, and Cosmetic Act and held to current good manufacturing practice (CGMP) standards—in order to dispense those medications to patients pursuant to valid prescriptions.

This distinction is important. In such cases, the 503A pharmacy remains responsible for the patient-specific prescription, and the product is not further sold or transferred. The product is dispensed directly to a patient, fulfilling the core purpose of a pharmacy under both state and federal law.

While Nebraska statute does not define "resale" explicitly within the Pharmacy Practice Act, interpretations drawn from other statutes (e.g., the Uniform Controlled Substances Act and the Wholesale Drug Distributor Licensing Act) suggest that "resale" refers to transferring products to another party for commercial sale or distribution—not dispensing to an end user.

Furthermore, the FDA has acknowledged in its draft 2023 guidance on outsourcing facilities that 503B-prepared medications may be distributed to 503A pharmacies for patient-specific dispensing under valid prescriptions, provided that all appropriate federal and state licensing requirements are met. While 503B labeling must include "not for resale" pursuant to Section 503B(a)(10), the FDA has clarified in this draft guidance that this does not prohibit patient-specific dispensing by a 503A pharmacy.

Disallowing these transactions creates unnecessary barriers to patient care and limits access to high-quality compounded medications prepared under CGMP conditions. Many 503A pharmacies rely on 503B facilities to meet fluctuating demand, respond to supply chain disruptions, or supplement in-

house capabilities—especially for sterile or complex compounds. This is especially significant in Nebraska, where only a handful of compounding pharmacies engage in compounding sterile preparations.

We respectfully urge the Nebraska Board of Pharmacy to reconsider its interpretation of Neb. Rev. Stat. §38-2867.01 in light of this broader regulatory context and the evolving federal guidance. Allowing 503A pharmacies to source from 503B outsourcing facilities for patient-specific dispensing enhances patient safety, ensures continuity of care, and supports the responsible practice of compounding.

We would welcome the opportunity to engage in further dialogue with the Board and provide additional information. Please do not hesitate to contact us with any questions or to schedule a conversation.

Sincerely,

Scott Brunner, CAE
Chief Executive Officer

The Alliance for Pharmacy Compounding is the voice for pharmacy compounding, representing more than 600 compounding small businesses – including compounding pharmacists and technicians in both 503A and 503B settings – as well as prescribers, educators, researchers, and suppliers.